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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,765	04/20/2004	James Fink	016770-007100US	5232

1095 7590 12/28/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
OSTRUP, CLINTON T	

ART UNIT	PAPER NUMBER
3771	

MAIL DATE	DELIVERY MODE
12/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,765	FINK ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/30/09 & 9/25/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-31* is/are pending in the application.

4a) Of the above claim(s) *21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20 and 22-31* is/are rejected.

7)☒ Claim(s) *22,23 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 30, 2009 has been entered.

As directed by the amendment, claims 20 and 24 have been amended and claim 21 has been withdrawn from consideration. Thus, claims 20-31 are pending in this application and claim 21 has been withdrawn from consideration.

Claim Objections

1. Claims 22-23 and 31 are objected to because of the following informalities: Claims 22-23 and 31 depend directly or indirectly from claim 21, which applicant has withdrawn from consideration. For examination purposes, claim 22 was considered to depend from claim 20. Since claims 23 and 31 depend from claim 22, this provides a proper sequence of dependent claims; however, appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heinonen (6,530,370) and further in view of Hamilton et al., (2002/0162553).

4. Heinonen discloses a nebulizer apparatus and method of using a nebulizer apparatus in conjunction with a breathing circuit. Heinonen discloses using the apparatus for respiratory therapy (col. 1, lines 15-16) comprising the steps of: providing a pressure-assisted breathing system (figure 1) having a pressure-generating circuit (8) and a respiratory circuit (18) adapted to be coupled to a patient interface device (col. 4, lines 52-64), wherein the pressure-generating circuit (8) contains a first gas flow (from 8) and wherein the respiratory circuit (18) contains a second gas flow (col. 5, lines 24-39) of lower volume than the first gas flow (from 8); engaging the patient interface device (mouthpiece, facemask, or endotracheal tube) with the patient's respiratory system; and introducing an aerosolized medicament (via nebulizer 1) into the second gas flow by a vibrating aperture nebulizer (col. 5, lines 53-67) coupled to the respiratory circuit (18), wherein the nebulizer is positioned and configured (it is close to the mouthpiece, facemask, or endotracheal tube) to avoid dilution of the aerosolized medicament that is delivered to the patient's respiratory system.

However, Heinonen lacks the specific teaching of utilizing the device with a continuous positive pressure.

Hamilton teaches a portable positive pressure breathing apparatus with a nebulizer directly connected to its distal end. See: abstract and figure 1.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the used the nebulizer disclosed by Heinonen is a positive pressure gas delivery system, as taught by Hamilton in order to provide aerosolized delivery of medicaments to patients with sleep apnea while they are asleep.

5. Claim 22-23 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinonen (6,530,370), in view of Hamilton et al. (2002/0162553), as applied to claim 20 above, and further in view of Power (2002/0002975).

6. The combined references teach all the limitations of claim 22, except the aerosolized medicament the nebulizer comprises a reservoir having a capacity equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system.

7. Power teaches a nebulizer that has a reservoir (2) having a capacity (maximum volume of about 10 ml) equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system. See: [0066]-[0072].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the reservoir capacity of the nebulizer of the combined references, to have a reservoir with a capacity equal to one unit dose of medicament, as taught Power, in order to provide a user with a single dose of medicament during the duration of positive pressure ventilation.

Regarding claims 23 and 30, Power teaches a reservoir (2) having a maximum volume of about 10 ml, which is inclusive of any volume less than 10 ml. Moreover, modifying the dosage size to be 4ml or less is an obvious modification that a practitioner would perform based upon a patient's physical attributes such as size, weight and age.

8. Claims 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinonen (6,530,370), Hamilton et al. (2002/0162553) and Power (2002/0002975) and further in view of Merrill (3,715,432).

9. The combined references disclose a device and method of using a device as claimed, but lack the specific teaching of using a liquid surfactant, as claimed.

10. Merrill teaches aerosolizing aqueous dispersions of lecithin (also known as phosphatidylcholine, a well known phospholipid used in the respiratory arts for treating lung disorders) using an ultrasonic nebulizer. Merrill described how the nebulized dispersions are in the submicron diameter and can be readily transmitted to the alveoli of the lungs. See: col. 1, lines 25-45 and abstract.

11. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the treatment method disclosed by the combined references by using phospholipids as taught by Merrill in order to provide a unit dose nebulizer dose capable of administering a well known medicament in submicron diameters.

Regarding claim 25, Merrill teaches using the lecithin, also known as phosphatidylcholine, a well known phospholipid.

Regarding claim 26, the amount of aerosolized surfactant introduced into the system is a function of the nebulizer used. Power teaches an ultrasonic nebulizer and this is the specific nebulizer disclosed by applicant as being useful in their invention (See: applicants specification at page 2, [0004] and page 9 [0032] wherein Powers is equivalent to US 6,615,824). Absent a showing of unexpected results obtained with the

claimed nebulizer, it is reasonable to expect the nebulizer disclosed by Power to have similar percentages of aerosolized medicament in use.

12. Regarding claim 27, Power teaches a nebulizer that has a reservoir (2) having a capacity (maximum volume of about 10 ml) equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system. See: [0066]-[0072].

Regarding claim 28, Merrill teaches dosages of 10 milligrams or less. See: col. 1, lines 49-62.

As to claims 29 and 30, Heinonen discloses a mouthpiece, facemask, or endotracheal tube. See: col. 4, lines 62-64.

Response to Arguments

13. Applicant's arguments filed July 30, 2009 to the rejection of claims 20 and 22-31 have been fully considered and found persuasive; therefore, the said rejections have been withdrawn.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

15. Grychowski et al (2005/0039746); Langenback (5,666,946); Alston et al (2005/0139211); Tsukashima et al (2004/0210153); Hoenig (4,323,064); Greenfield (3,490,452); Gilroy (2,693,178); and Kock et al (5,443,059) which all teach respiratory devices that deliver nebulized medicaments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771